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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,979	03/25/2004	Qiong Cheng	CL2360USNA	8665

23906 7590 11/05/2004

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EXAMINER	
KOROMA, BARBA M	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/808,979	CHENG ET AL.	
	Examiner	Art Unit	
	Barba M. Koroma	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1- 3, 7-13, 15, 17, and 18, drawn to an isolated nucleic acid molecule encoding a carotenoid biosynthetic enzyme, a nucleic acid isolated from strain DC260, a chimeric gene operably linked to regulatory sequences, and a transformed host cell, classified in class 536, subclass 23.6, for example.

II. Claims 4 and 5, drawn to a polypeptide, classified in class 530, subclass 300, for example.

III. Claims 6, 14, and 16-18, drawn to an isolated nucleic acid of SEQ ID No. 18, or isolated nucleic acid having at least 95% sequence identity to SEQ ID no. 18, or a transformed host or vector comprising the isolated nucleic acid of SEQ ID No.18, classified in class 435, subclass 320.1, for example.

IV. Claims 19, and 21-26, drawn to a method of carotenoid biosynthesis in a transformed host cell, classified in class 435, subclass 69.1 for example.

V. Claims 20-26, drawn to a method for the production of carotenoid compounds, classified in class 435, subclass 419, for example.

VI. Claim 28, drawn to a method of regulating carotenoid biosynthesis wherein a carotenoid gene is over-expressed on a multi-copy plasmid, classified in class 800, subclass 278, for example.

VII. Claim 30, drawn to a method of regulating carotenoid biosynthesis wherein a carotenoid gene is expressed in anti-sense orientation, classified in class 800, subclass 286, for example.

VIII. Claim 31, drawn to a method of regulating carotenoid biosynthesis wherein a carotenoid gene is disrupted by insertion of foreign DNA into the coding region, classified in class 435, subclass 410, for example.

IX. Claim 32, drawn to strain DC260 comprising the 16s rDNA sequence as set forth in SEQ ID No. 16, classified in class 435, subclass 471, for example.

Claims 27 and 29 link inventions VI-VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 27 and 29. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting

rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct each from the other because:

Inventions of Group I (nucleic acid) and Group II (polypeptide) are different products. They differ physically and chemically from each other and could be used to make other and materially different products.

Inventions of Group I (nucleic acid) and Group III (nucleic acid) are different products. The product of group I is not required to make the product of Group III. The product of group III can be made using different nucleotide bases. The nucleotide sequence of Group I are patentably distinct because the individual sequences of Group I do not require all of the coding sequences of the nucleotide sequences of Group II. Further, the sequences of Groups I and II can be made by processes not requiring each other such as chemical synthesis.

Inventions of Group I (nucleic acid) and Group IV-VIII (method of carotenoid biosynthesis). Inventions I and IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group I can be used in a different process such as in a method of hybridization.

Inventions Group I (nucleic acid) and Group IX (a cell strain) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids can be used in hybridization.

Inventions of Group II (polypeptide) and Group III (nucleic acids) are different products. The product of group I is not required to make the product of Group III.

Inventions of Group II (polypeptide) and Groups IV-VIII (methods of carotenoid biosynthesis) are patentably distinct. The polypeptides of Group II are not required starting materials for the methods of Group IV-VIII. Inventions IV-VIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group II can be used in a different process such as in a method of hybridization.

The products of Groups II (polypeptides) and IX are patentably distinct. One is a polypeptide and another is a bacterial strain.

Inventions Group III (nucleic acids) and Groups IV-VIII (methods of carotenoid biosynthesis) are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group III can be used in a different process such as in a method of hybridization.

Inventions of Group III (nucleic acid) and Group IX (a cell strain) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of Group I encodes products involved with carotenoid biosynthesis, whereas the product of Group IX is a cell or bacterial strain.

Inventions of Groups IV and Groups V-VIII are patentably distinct methods of carotenoid biosynthesis and regulation. The methods require different starting materials.

Inventions of Groups V and Groups VI-VIII are patentably distinct methods of carotenoid biosynthesis and regulation. The methods require different starting materials.

Inventions of Groups VI and Groups VII-VIII are patentably distinct methods of carotenoid biosynthesis and regulation. The methods require different starting materials.

Inventions of Groups VII and Group VIII are patentably distinct methods of carotenoid biosynthesis and regulation. The methods require different starting materials.

Inventions of Groups IV-VIII and Group IX are unrelated. The cell strain is not a starting material for the method of Group VIII.

Applicants are reminded that different nucleotide sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute **independent and distinct** inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

If Group I is elected, Applicant is required to select one nucleotide and one corresponding polypeptide sequence from SEQ ID Nos: 2, 4, 6, 8, 10, and 12. This requirement is not to be construed as a requirement for an election of species, since each nucleotide sequence is not a member of single genus of invention, but constitutes an independent and patentably distinct invention.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter, and because the search required for one Group may not reveal information on the other groups, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Barba M. Koroma, whose telephone number is 571-272-0899. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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